Clinical Guideline

Oscar Clinical Guideline: Xiidra (lifitegrast) (PG197, Ver. 2)

Xiidra (lifitegrast)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Dry eye disease, also known as keratoconjunctivitis sicca, is a multifactorial condition characterized by ocular discomfort, visual disturbance, and tear film instability with potential damage to the ocular surface. It is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface. Dry eye disease can be caused by aqueous tear deficiency, excessive tear evaporation, or an underlying inflammatory condition. Risk factors include older age, female sex, use of certain medications (e.g. anticholinergics, antihistamines), ocular surgery, and systemic inflammatory diseases like Sjogren's syndrome.

Management of dry eye disease typically starts with education, environmental modifications, and lubricating therapies like artificial tears and gels. Prescription options include anti-inflammatory therapies like cyclosporine ophthalmic emulsion (Restasis), corticosteroid eye drops for short-term use, and the lymphocyte function-associated antigen-1 (LFA-1) antagonist lifitegrast (Xiidra). Other options are punctal plugs to conserve tears, autologous serum tears, and procedures like thermal pulsation.

Definitions

"**Aqueous tear deficiency**" refers to reduced production of the aqueous (water) component of tears, leading to dry eye disease.

"**Keratoconjunctivitis sicca**"is a condition marked by dryness of the conjunctiva (the membrane lining the eyelids and covering the white part of the eye) and the cornea (the clear, front surface of the eye).

"**Punctal plugs**" are small devices inserted into the tear drainage ducts to conserve tears and treat dry eye disease.

"**Sjögren's syndrome**"is a chronic autoimmune disorder characterized by dryness of the eyes, mouth, and other mucous membranes due to the body's immune system mistakenly attacking its own cells and tissues.

"**Thermal pulsation**" is a procedure that applies heat and pressure to the eyelids to help treat dry eye associated with meibomian gland dysfunction.

Medical Necessity Criteria for Initial Authorization

The Plan considers **Xiidra (lifitegrast)** medically necessary when **ALL** of the following criteria are met:

1. The member is 17 years of age or older; ***AND***
2. The member has at least one of the following documented diagnosis:
    a. Dry eye disease, such as:
        i. Chronic dry eye disease***; or***
        ii. Keratitis sicca***; or***
        iii. Keratoconjunctivitis sicca***; or***
        iv. Xerophthalmia***; or***
        v. Any other form of dry eye syndrome***; or***
    b. Dry eye conditions due to systemic inflammatory diseases, such as:
        i. Sjögren's Syndrome***; or***
        ii. Other systemic inflammatory diseases resulting in dry eye conditions (e.g., autoimmune thyroid disease, rheumatoid arthritis)***; or***
    c. Dry eye conditions due to ocular surface diseases, such as:
        i. Ocular Graft vs. Host Disease***; or***
        ii. Corneal Transplant Rejection***; or***

iii. Other ocular surface diseases resulting in dry eye conditions (e.g., blepharitis, conjunctivitis, herpes simplex keratitis); ***AND***

3. Clinical chart documentation is provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met, Xiidra (lifitegrast) will be approved for 12 months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months will be granted if **BOTH** of the following are met:

1. the member continues to meet the applicable Initial Authorization criteria***; AND***
2. chart documentation indicates **EITHER** of the following:
    a. The member has shown a clinical improvement⇅ in symptoms since starting the requested medication; ***or***
    b. The member has experienced disease stability⇅ since starting the requested medication.

⇅*Note: Clinical improvement may be characterized by reduction in signs and symptoms such as ocular discomfort, burning, or dryness, and/or an increase in tear production as measured by standardized tests such as Schirmer's test or tear break-up time. Disease stability refers to a halt in disease progression, with signs and symptoms remaining consistent and not worsening over time. These should be supported by the medical documentation.*

Experimental or Investigational / Not Medically Necessary

Xiidra (lifitegrast) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Additionally, the safety and efficacy of Xiidra (lifitegrast) has not been established in patients under the age of 17 years.

References

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Clinical Guideline Revision / History Information

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